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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/633,657 | 08/05/2003 | Chieh-Fu Chen | 5277-0101PUS1 | 5467 |
| 2292 7590 10/15/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | EXAMINER HOFFMAN, SUSAN COE | |
| | | | ART UNIT 1655 | PAPER NUMBER |
| | | | NOTIFICATION DATE 10/15/2007 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/633,657

Applicant(s)

CHEN ET AL.

Examiner

Susan Coe Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed July 30, 2007 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 6 has been added.
3. Claims 1-6 are pending.
4. In the reply filed on December 14, 2005, applicant elected Group I without traverse.
5. Claim 2 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 14, 2005.
6. Claims 1 and 3-6 are examined on the merits.

Claim Rejections - 35 USC § 102/103

7. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chou et al. (Journal of Chinese Medicine (March 2002), vol. 13, no. 1, pp. 39-48) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claims are patentable over the reference because the reference does not teach using methanol in the extraction step. However, as discussed in the previous Office action, applicant's claims are drawn to product-by-process claims. Regarding product-by-process claims, MPEP § 2113 states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of

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the statute is appropriate...A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

The product of Chou reasonably appears to be the same as the product claimed by applicant because the product of Chou is an extract from *Stephania tetrandra* roots that contains tetrandrine, fangchinoline, cyclanoline, and oblongine. Furthermore, figure 2 of Chou shows the HPLC data which show the retention times for tetrandrine, fangchinoline, cyclanoline, and oblongine. The HPLC times shown in Chou are similar if not identical to those claimed by applicant in claim 5. This further supports a conclusion that the composition of Chou is the same composition. Applicant has not demonstrated that the addition of a methanol step to the extraction process creates a patentably distinct product from Chou. Thus, the claims are still properly anticipated or rendered obvious by Chou.

8. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wang (US Pat. No. 6,218,541) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claims are patentable over the reference because the reference does not teach using methanol in the extraction step. However, as discussed in the previous Office action, applicant's claims are drawn to product-by-process claims. Regarding product-by-process claims, MPEP § 2113 states that:

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"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

The reference discloses extract which appears to be identical to the presently claimed extract, based on the fact that the both the reference extract and the claimed extract are *S. tetrandra* extracts created using ethanolic extraction and both contain tetrandrine, fangchinoline, and cyclanoline. Consequently, the claimed extract appears to be anticipated by the reference. Applicant has not demonstrated that the addition of a methanol step to the extraction process creates a patentably distinct product from Wang. Thus, the claims are still properly anticipated or rendered obvious by Wang.

Claim Rejections - 35 USC § 103

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pyun (WO 95/33473).

Pyun teaches an extract from *S. tetrandra* that is made by extracting the root of the plant with methanol at 50 to 70 degrees C (see page 5, lines 12-15). The reference does not specifically teach extracting with methanol at 80 degrees C. However, the temperature for extraction is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is

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not inventive to discover the optimum or workable ranges by routine experimentation." In *re* Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches that a range of temperatures can be used. In addition, the reference does teach that an extraction temperature as high as 100 degrees C can be used during extraction of the *S. tetrandra* (see page 26, claim 5). Thus, by teaching a range of temperatures, the reference acknowledges that the extraction temperature can be varied. Therefore, it would have been customary for an artisan of ordinary skill to determine the optimal extraction temperature to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of extraction temperature would have been obvious at the time of applicant's invention.

10. Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou in view of Pyun.

Chou teaches an extract from *S. tetrandra* roots that contain tetrandrine, fangchinoline, cyclanoline, and oblongine. The extract is created by extracting the roots with 95% ethanol 3 or 5 times at 80 degrees Celsius (see page 41, "Experimental" section). The reference does not teach using methanol in the extraction. However, Pyun teaches that both ethanol and methanol can be used interchangeably to extract *S. tetrandra* roots (see page 5, lines 5-6). Thus, an artisan of ordinary skill would have reasonably expected that methanol could be substituted for ethanol in one of the ethanolic extractions taught by Chou. This reasonable expectation of success would have motivated the artisan to modify the extraction taught by Chou to include a methanolic extraction step.

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11. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Susan Cogburn Hoffman
Primary Examiner
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